UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

NOVO NORDISK, INC.,)
Plaintiff,)
v.) No. 3:23-cv-00668
DCA PHARMACY,)
Defendant.)

MEMORANDUM OPINION

Before the Court is Defendant DCA Pharmacy's Motion to Dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). (See Doc. Nos. 38, 39). Plaintiff Novo Nordisk, Inc. filed a response in opposition (Doc. No. 40), and DCA replied (Doc. No. 42). For the following reasons, DCA's motion will be denied without prejudice.

I. FACTUAL ALLEGATIONS AND BACKGROUND¹

Novo describes itself as "a leading healthcare company," and the only company with approval from the Food and Drug Administration ("FDA") to produce medicine containing the molecule "semaglutide." (Doc. No. 1 ¶¶ 1, 3). Semaglutide is the primary ingredient for three of Novo's prescription medications: Wegovy®, Ozempic®, and Rybelsus.® (Id. ¶ 2). According to Novo, these three medications "are the only FDA-approved drugs containing semaglutide." (Id. ¶ 19).

On July 6, 2023, Novo brought this lawsuit against DCA, alleging that DCA "markets and sells to patients certain drug products that purport to contain 'semaglutide' and are not FDA

¹ The relevant facts necessary to resolve the pending motion to dismiss are drawn only from the Complaint (Doc. No. 1) and are assumed to be true for purposes of ruling on the motion. <u>See</u> Erickson v. Pardus, 551 U.S. 89, 94 (2007).

approved." (Id. ¶ 9). Novo claims that DCA, by doing so, has engaged in unfair or deceptive acts or practices, in violation of the Tennessee Consumer Protection Act ("TCPA"), Tenn. Code Ann. § 47-18-104(a), and "has caused [Novo] to suffer an ascertainable loss in the form of lost customers, as well as loss of goodwill and damage to [Novo's] reputation." (Doc. No. 1 ¶ 41). Novo seeks (i) a permanent injunction enjoining DCA from selling products with semaglutide, (ii) a declaratory judgment that DCA violated the TCPA, and (iii) attorney's fees and costs. (Id. ¶ 43).

On August 10, 2023, DCA filed a motion to dismiss under Rules 12(b)(2) and 12(b)(6), arguing that Tenn. Code Ann. § 48-25-102 barred Novo from maintaining this lawsuit because it was "a foreign corporation transacting business" in Tennessee without a "certificate of authority." (See Doc. No. 15). After that motion was fully briefed, Novo obtained and filed the requisite certificate of authority (see Doc. No. 35), and DCA responded by moving to withdraw its motion to dismiss as moot (see Doc. No. 36). The Court granted DCA's request to withdraw, and the Clerk terminated the motion as pending on the docket. (See Doc. No. 37).

On January 31, 2024, DCA filed a second motion to dismiss under Rules 12(b)(1) and 12(b)(6). (Doc. No. 38). This time, DCA argues that Novo lacks standing, and that the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts Novo's TCPA claim. (Id. at 1). In its opposition, Novo argues that it has standing to allege economic injuries and that DCA's second motion to dismiss is procedurally improper under Rule 12(g)(2). (See Doc. No. 40 at 1–2). Because DCA's two overarching arguments involve different legal standards, the Court will address them as separate motions below.

II. MOTION TO DISMISS UNDER RULE 12(B)(1) FOR LACK OF STANDING

A motion to dismiss for lack of standing is properly characterized as a motion to dismiss for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). Forest City Residential Mgmt., Inc. ex rel. Plymouth Square Ltd. Dividend Hous. Ass'n v. Beasley, 71 F.

Supp. 3d 715, 722–23 (E.D. Mich. 2014) (citing Stalley v. Methodist Healthcare, 517 F.3d 911, 916 (6th Cir. 2008)). "Where a defendant challenges a plaintiff's standing to bring suit, the Court should first consider whether it has subject matter jurisdiction pursuant to Rule 12(b)(1) before it considers the substantive merits of a pleading pursuant to Rule 12(b)(6)." Diversicare v. Glisson, 2017 WL 4873510, at *4 (E.D. Ky. Oct. 27, 2017) (citing Bell v. Hood, 327 U.S. 678, 682 (1946)).

To establish the threshold requirement of Article III standing at the pleading stage, the plaintiff bears the burden of alleging facts that plausibly demonstrate that it "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992)); see also Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 185 (2000); Soehnlen v. Fleet Owners Ins. Fund, 844 F.3d 576, 581 (6th Cir. 2016). A plaintiff seeking injunctive relief must make an additional showing that it suffered "both past injury and a real and immediate threat of future injury." Mosley v. Kohl's Dep't. Stores, Inc., 942 F.3d 752, 756 (6th Cir. 2019) (citations and internal quotation marks omitted) (emphasis added).

DCA argues that this case should be dismissed for lack of standing because Novo has neither alleged that it suffered a qualifying injury-in-fact to obtain injunctive relief, nor that there is any causal connection between an alleged injury and DCA's conduct. (See Doc. No. 39 at 4-5). According to DCA, "the only harm that [Novo] alleges is merely competition, which is legitimate and, indeed, explicitly greenlit by applicable FDA regulators." (Id. at 5). Novo responds that, as alleged in the Complaint, DCA's "unlawful sales substantially risk loss of goodwill and damage to Novo's reputation" and "cause Novo to suffer an ascertainable loss in the form of lost customers." (Doc. No. 40 at 1).

The injury-in-fact requirement merely "serves to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem." United States v. Students Challenging Regulatory Agency Procedures (SCRAP), 412 U.S. 669, 690 n.14 (1973) (citation omitted); see also NB ex rel. Peacock v. District of Columbia, 682 F.3d 77, 82 (D.C. Cir. 2012) (noting that the burden imposed on plaintiffs to establish standing is not onerous). Here, viewing the Complaint in the light most favorable to Novo, the Court finds that Novo has met its prima facie burden to allege an injury-in-fact for standing. For example, the Court may reasonably infer from the Complaint that Novo and DCA compete directly in the United States over the sale of products containing semaglutide. The Complaint also alleges that Novo continues to lose customers because of DCA's unfair, deceptive, and ongoing practice of unlawfully selling products containing semaglutide without FDA approval. (Doc. No. 1 ¶¶ 37, 41–42). To remedy this alleged injury, Novo seeks an injunction against DCA to protect against any future harm to its sales, customers, goodwill, and reputation. (Id. at Conclusion and Prayer for Relief). These factual allegations tie Novo's alleged economic loss to DCA's conduct, and therefore Novo has a direct stake in remedying its alleged injuries for purposes of standing. See Adams v. Watson, 10 F.3d 915, 921–25 (1st Cir. 1993).

As both parties also acknowledge, the Middle District of Florida encountered a nearly identical standing argument in Novo Nordisk, Inc. v. Brooksville Pharms. Inc., 2023 WL 7385819 (M.D. Fla. Nov. 8, 2023). There, the court found that Novo "is the only pharmaceutical company with express FDA approval to create, manufacture, and sell drugs containing semaglutide," and that Novo is in economic competition with the defendant who "also creates, manufactures, and sells drugs that contain semaglutide in the same geographical areas where [Novo] conducts business." Id. at *2. Based on the complaint's allegations in Brooksville, the court found that Novo had standing because it could "reasonably infer that any sale by Defendant reduces, and will continue to reduce, [Novo's] individual profits." Id. The Court finds Brooksville persuasive and likewise finds Novo's alleged "present and future economic injury-in-fact" sufficient to support standing. See id.

Accordingly, the Court will deny DCA's Rule 12(b)(1) motion to dismiss for lack of standing.

III. MOTION TO DISMISS UNDER RULE 12(B)(6) FOR FAILURE TO STATE A **CLAIM**

DCA next argues that the Court should dismiss the Complaint because Novo's TCPA claim is preempted by the FDCA. (See Doc. No. 39 at 6). "A motion to dismiss based on federal preemption is properly characterized as one under Rule 12(b)(6)." Fast Access Specialty Therapeutics, LLC v. UnitedHealth Grp., Inc., 532 F. Supp. 3d 956, 962 (S.D. Cal. 2021). Rather than respond to DCA's substantive preemption argument, Novo argues that the Court should deny DCA's 12(b)(6) motion as "squarely barred" under Rule 12(g)(2). (See Doc. No. 40 at 2 n.1). Specifically, Novo contends that Rule 12(g)(2) prohibits DCA from raising its preemption argument for the first time now because DCA could have raised that argument in its prior (and now voluntarily withdrawn) motion to dismiss. (<u>Id.</u> at 5–7).

Rule 12(g)(2) provides that, subject to limited exceptions in Rule 12(h) not relevant here, "a party that makes a motion under [Rule 12] must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion." Fed. R. Civ. P. 12(g)(2); Means v. United States Conf. of Cath. Bishops, 836 F.3d 643, 648 (6th Cir. 2016). DCA does not dispute that its preemption argument was available when it filed its first motion to dismiss. Thus, the plain language of Rule 12(g)(2) appears to support Novo's position and requires the Court to deny DCA's successive motion to dismiss as procedurally improper. Several decisions from this district have come to the same conclusion and refused to consider successive Rule 12 motions pursuant to Rule 12(g)(2). See JRS Partners, GP v. Leech Tishman Fuscaldo & Lampl, LLC, 615 F. Supp. 3d 750, 779–80 (M.D. Tenn. 2022); Tractor Supply Co. v. ACE Am. Ins. Co., 2022 WL 4821988, at *3 (M.D. Tenn. Sept. 30, 2022); Hamm v. Wyndham Resort Dev. Corp., 2020 WL 5995050, at *6 (M.D. Tenn. Oct. 9, 2020); see also Dowell v. Bernhardt, 2020 WL 13644144, at *2 (M.D. Tenn. Apr. 13, 2020) (analyzing Rule 12(g)(2) in the context of a Rule 60(b) motion).

Not all courts have strictly construed Rule 12(g)(2), however, and "a line of precedent exists in which the district courts have been willing to overlook a 12(g) defect where doing so would better serve the purpose underlying subdivision (g)." Blick v. Ann Arbor Pub. Sch. Dist., 2021 WL 10132110, at *2 (E.D. Mich. Sept. 30, 2021) (Dawkins, J.) (quoting <u>Davis v. City of</u> Dearborn, 2010 WL 3476242, at *4 (E.D. Mich. Sept. 2, 2010)). These cases suggest that "[w]here there is no evidence that a successive Rule 12 motion would create an unjust delay or facilitate an abuse in motion practice, courts have been willing to excuse 12(g) problems and address the merits of the defendant's motion to dismiss." <u>Davis</u>, 2010 WL 3476242, at *4 (collecting cases). After all, "[t]he policy behind Rule 12(g) is to prevent piecemeal litigation in which a defendant moves to dismiss on one ground, loses, then files a second motion on another ground." Ennenga v. Starns, 677 F.3d 766, 773 (7th Cir. 2012). Some appellate courts—namely, the Third, Ninth, and Tenth Circuits—have also expressed a willingness to "forgive" a district court's choice to consider a latefiled Rule 12(b)(6) motion. Leyse v. Bank of Am. Nat. Ass'n, 804 F.3d 316, 321–22 (3d Cir. 2015); In re Apple iPhone Antitrust Litig., 846 F.3d 313, 318–19 (9th Cir. 2017); Albers v. Bd. of Cnty. Comm'rs of Jefferson Cnty., 771 F.2d 697, 702 (10th Cir. 2014).

Despite this line of case law, the Court declines DCA's invitation to follow the old maxim

that it is better to ask (the Sixth Circuit) for forgiveness than to ask (the Federal Rules) for permission. DCA's plea to judicial economy is well taken, as it would make practical sense for the Court to consider DCA's motion here and now instead of waiting for DCA to file a nearly identical post-answer Rule 12(c) motion later. See Zambon v. Dollar Tree Pigeon Forge, 2018 WL 11463594, at *2 (E.D. Tenn. Feb. 13, 2018) (noting that "there is little practical difference between permitting a second pre-answer Rule 12(b) motion and awaiting an inevitable Rule 12(c) motion on the same grounds, at least absent any evident danger of prejudice or undue delay"). But Rule 12(g)(2) says what it says, and, under these circumstances, the Court is unwilling to commit an intentional procedural error in the interest of judicial economy just because the Sixth Circuit may forgive that error on appeal. See Dowell, 2020 WL 13644144, at *2 ("None of these cases stands for the proposition that it is erroneous for a district court to refuse to permit a second motion to dismiss; if anything, some stand for the proposition that it may be error [under Rule 12(g)(2)] to permit the second motion to dismiss.").

DCA argues in its reply brief that Rule 12(g)(2) should not apply here because DCA voluntarily withdrew its first motion to dismiss before the Court considered it on the merits. (Doc. No. 42 at 3). DCA has not cited, and the Court is not aware of, any legal authority holding that a party may file a successive Rule 12(b) motion as long as the moving party withdraws its first fullybriefed motion before the Court rules. Nor is the Court compelled to create such a rule here, particularly where the parties were represented by counsel and DCA does not claim it filed its first motion inadvertently. The Court likens this scenario to a situation where the defendant files a motion to dismiss and then the plaintiff responds by filing an amended complaint. Courts have held that "[t]he filing of an amended complaint" does not create an exception to Rule 12(g)(2) "with respect to claims in the amended complaint that were in the original complaint—and thus

were subject to being challenged, in the motion to dismiss the original complaint, via the same defenses that the defendant seeks to bring for the first time in a motion to dismiss the amended complaint." JRS Partners, 615 F. Supp. 3d at 779-80. Under those same principles, the Court concludes that Rule 12(g)(2) procedurally bars DCA's instant Rule 12(b)(6) motion.

As the Court indicated above, this win for Novo merely means that DCA can reraise the exact same arguments on a motion under Rule 12(c) for judgment on the pleadings, on a motion for summary judgment, or at trial. See Fed. R. Civ. P. 12(h); see also Zambon, 2018 WL 11463594, at *1 (citing 5C Charles Alan Wright et al., Federal Practice & Procedure § 1385 (3d ed. 1998)); Bolger v. Woods, 306 F. Supp. 3d 985, 995 (S.D. Ohio 2018) (concluding "that a party may file a Rule 12(c) motion for judgment on the pleadings at a later stage in the litigation, even if the party has filed a previous motion under Rule 12"). DCA previewed that, if the Court denies its pending Rule 12(b)(6) motion under Rule 12(g)(2), it intends to "file an answer and convert [its] motion into a [Rule] 12(c) motion." (Doc. No. 39 at 1 n.1). To the extent DCA files a future Rule 12(c) motion based on federal preemption, the Court expects both parties to address whether the holding and reasoning in <u>Brooksville</u>, 2023 WL 7385819, is dispositive here.

IV. **CONCLUSION**

For the foregoing reasons, DCA's Motion to Dismiss (Doc. No. 38) will be denied without prejudice to DCA reraising its preemption argument in a procedural posture permitted by Rule 12(h).

An appropriate Order will enter.